UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES OF AMERICA, *ex rel.*	
MARC YOUNG, JEREMY W. BRIGGS, and JOSEPH B. LAWRENCE,	**Civil Action No. 1: 17- CV-373**
	UNITED STATES DISTRICT JUDGE SUSAN J. DLOTT
Plaintiffs and Relators,	
	SECOND AMENDED COMPLAINT
	Filed under seal pursuant to 31 U.S.C. § 3730(b)(2)
v.	
GOLDEN STATE MEDICAL SUPPLY, INC.,	
	DO NOT SERVE
Defendant.	**DO NOT PUT ON PACER**

Relators bring this action on behalf of the United States and on their own behalf and allege the following:

I. INTRODUCTION

1. This is a *qui tam* action brought by Relators Marc Young, Jeremy W. Briggs, and Joseph B. Lawrence ("**Relators**") on behalf of the United States against Defendant Golden State Medical Supply, Inc. ("**Defendant GSMS**" or "**GSMS**") to recover damages and civil penalties arising from false or fraudulent statements, records, and claims made, used, or caused to be made or used by Defendant GSMS in violation of the False Claims Act, 31 U.S.C. § 3729 *et seq*.

2. Defendant GSMS is a generic pharmaceutical company located in Camarillo, California.

3. Defendant GSMS falsely represented and/or certified the country of origin for pharmaceutical products as being from Trade Agreements Act ("**TAA**") designated countries in order to obtain United States Government contracts, and knowingly sold or caused the sale of non-TAA compliant pharmaceutical products to the United States in violation of the express terms of those Government contracts. The Government contracts at issue include Contract No. VA797P-13-C-0030 (**metoprolol succinate**); Contract No. VA797P-14-C-0004 (**carbamazapine IR**); Contract No. SPE2D2-16-D-0031 (**quetiapine fumarate**); Contract No. VA797P-16-C-0061(**ursodiol**); Contract No. VA797P-16-C-0063 (**acyclovir**); Contract No. VA797P-16-C-0078 (**losartan potassium**); Contract No. VA797P-13-C-0011 (**labetalol HCL**); Contract No. SPE2D2-14-D-0005 (**fexofenadine**); Contract No. VA797P-14-C-0003 (**methocarbamol**); Contract No. VA797P-15-C-0029 (**estradiol**); Contract No. VA797P-15-C-0050 (**topiramate**); Contract No. VA797P-16-C-0055 (**cefuroxime axetil**); Contract No. SPE2D2-14-D-0008 (**atenolol**); Contract No. SPE2D2-15-D-0025 (**bupropion XL**); and Contract No. VA797P-17-C-0005 (**tamoxifen citrate**) (collectively referred to as "**the Government contracts**").

4. Defendant GSMS has been perpetrating this fraud scheme since at least March 22, 2013 and continuing to the present.

5. Defendant GSMS carried out this fraudulent scheme across the United States by fraudulently bidding on and accepting orders on national Government contracts for the delivery of pharmaceutical products to pharmaceutical prime vendors for distribution to various governmental participants located throughout the United States, including medical treatment facilities, formularies, and eligible Government beneficiaries.

6. Defendant GSMS's unlawful acts in violation of the False Claims Act, as alleged herein, arise from submitting and/or causing the submission of false claims for payment to the federal government for pharmaceutical products and using materially false records and statements in support of those false claims. Defendant GSMS falsely certified and/or represented that its pharmaceutical products were from TAA-designated countries, failed to truthfully certify that its pharmaceutical products were from non-TAA designated countries, and knowingly submitted or caused to be submitted fraudulent information to the federal government concerning the country of origin of its pharmaceutical products for the purpose of unlawfully obtaining contracts and payments that it was not entitled to receive.

II. PARTIES

7. Plaintiff in this action is the United States of America, on whose behalf Relators bring their claims.

8. Relator Marc Young is a pharmacist with extensive project management and clinical pharmaceutical expertise. Relator Young has a Doctor of Pharmacy degree (PharmD) from Idaho State University and a Master's in Pharmacy Care Systems from Auburn University.

9. Relator Jeremy W. Briggs is a pharmacist with more than 15 years of experience in the pharmaceutical industry. Relator Briggs has a Doctor of Pharmacy degree (PharmD) from the University of Kansas and an MBA from the University of Texas, San Antonio.

10. Relator Joseph B. Lawrence is a pharmacist with more than 20 years of experience in the pharmaceutical industry. Relator Lawrence has a BS in Pharmacy from Southwestern Oklahoma State University, an MBA from the University of Phoenix, and a Doctor of Pharmacy degree (PharmD) from the University of Florida, College of Pharmacy.

11. Defendant Golden State Medical Supply, Inc. is a California corporation with its principal place of business in Camarillo, California. Golden State Medical Supply, Inc. also uses the trade name "GSMS, Incorporated" on its pharmaceutical labels and website, www.GSMS.us. As noted above, Defendant GSMS is a generic pharmaceutical company. While GSMS distributes the drugs and holds the contracts with the Government, it does not manufacture the drugs, instead it is simply the "Labeler" of the drugs at issue in this Complaint. Various other pharmaceutical companies are the "Manufacturers" of the drugs at issue.[1]

III. JURISDICTION AND VENUE

12. This action arises under the False Claims Act, 31 U.S.C. §§ 3729-3733. Relators bring this action pursuant to 31 U.S.C. § 3730(b)(1).

13. This Court has jurisdiction of the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1345.

14. This Court has personal jurisdiction over Defendant GSMS because GSMS is a United States corporation conducting business in the United States and, pursuant to 31 U.S.C. § 3732(a), because GSMS transacts business and committed acts proscribed by 31 U.S.C. § 3729 within this judicial district.

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[1] Acyclovir, carbamazepine, and quetiapine are manufactured by Apotex Inc. in Canada. Ursodiol, fexofenadine, and atenolol are manufactured by Mylan Pharmaceuticals Inc. in the United States. Losartan potassium is manufactured by Arrow Pharm (Malta) Ltd. in Malta. Metoprolol succinate is manufactured by Watson Laboratories, Inc. in the United States while labetalol HCL is manufactured by Watson Pharma Private Label in India. Cefuroxime axetil is manufactured by Lupin Limited in India. Finally, the following drugs are manufactured in the United States by the identified manufacturer as noted: Methocarbamol is manufactured by Austarpharma LLC; estradiol and tamoxifen citrate are manufactured by Teva Pharmaceuticals; topiramate is manufactured by Ascent or by InvaGen; and bupropion XL is manufactured by Actavis Laboratories FL, Inc. and/or is contract manufactured for Actavis by CMIC CMO USA CORP.

15. Venue is likewise proper in this judicial district under 31 U.S.C. § 3732(a) because Defendant GSMS transacts business and committed acts proscribed by 31 U.S.C. § 3729 in this judicial district and in this division.

16. Personal jurisdiction and venue are proper in this district (and for venue in this division) specifically because, in violation of the express terms of its government contracts, Defendant GSMS caused the distribution of and sought reimbursement for non-TAA compliant pharmaceutical products distributed to the following Government entities located within this district and this division: the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505. Defendant GSMS also transacted business and committed acts proscribed by 31 U.S.C. § 3729 in this district: 1) by submitting claims for payment to the United States and receiving payment from the United States through government pharmaceutical prime vendor Cardinal Health, Inc., (**"Cardinal Health**") which is located in this district in Dublin, Ohio; and 2) by distributing drugs pursuant to its Government Contract through government pharmaceutical prime vendors including Amerisource Bergen Drug Co. which maintains a distribution center in this district in Lockbourne, Ohio.

IV. THE FALSE CLAIMS ACT

17. The False Claims Act ("**FCA**") imposes liability upon any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval. . ." 31 U.S.C. § 3729(a)(1)(A).

18. The FCA also imposes liability upon any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim. . ." 31 U.S.C. § 3729(a)(1)(B).

19. The FCA defines "knowingly" to "mean that a person, with respect to information-(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). Proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B).

20. Under the FCA, the term "claim"

> (A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—
> (i) is presented to an officer, employee, or agent of the United States; or
> (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government —
> (I) provides or has provided any portion of the money or property requested or demanded; or
> (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and
> (B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property.

31 U.S.C. § 3729(b)(2).

21. Prior to filing this FCA action, Relators served upon the United States a copy of their Complaint and a written disclosure of substantially all material evidence and information they possessed, in accord with 31 U.S.C. § 3730(b)(2). Prior to filing the First Amended

Complaint, Relators served upon the United States copy of their First Amended Complaint and a supplemental written disclosure of substantially all material evidence and information they possessed. Prior to filing this Second Amended Complaint, Relators served upon the United States a copy of their Second Amended Complaint and a written Second Supplemental Disclosure Statement of substantially all material evidence and information they possessed.

22. There has been no prior "public[] disclos[ure]," as that term is used in 31 U.S.C. § 3730(e)(4)(A), of the allegations and transactions on which this FCA action is based.

23. Relators are "original source[s]" of the information upon which the allegations and transactions in this complaint are based, in accord with 31 U.S.C. § 3730(e)(4)(B).

V. DEFENDANT GSMS'S GOVERNMENT CONTRACTS REQUIRE COMPLIANCE WITH THE TRADE AGREEMENTS ACT

24. Pursuant to its government contracts, Defendant GSMS is required to provide pharmaceutical products that are end products of a Trade Agreements Act designated country.

25. In violation of the express terms of Defendant GSMS's government contracts, Defendant GSMS knowingly sold or caused the sale of pharmaceutical products from non-TAA designated countries to the United States.

A. Trade Agreements Act Requirements

26. The Trade Agreements Act ("**TAA**"), 19 U.S.C. § 2501 *et seq*., requires that certain products procured by the United States Government must have specific designated countries as their country of origin.[2]

[2] *See* 19 U.S.C. § 2512(a)(1)(A)(the President shall prohibit the procurement of products from non-designated foreign countries); *see also* 48 C.F.R. § 25.403(c)(1) (Under the TAA, the United States is to acquire only U.S.-made or designated country end products, for acquisitions covered by the World Trade Organization Government Procurement Agreement); 48 C.F.R. § 225.403(c)(same).

27. The TAA was enacted, in part, "to foster the growth and maintenance of an open world trading system" and "to expand opportunities for the commerce of the United States in international trade . . . ."[3]

28. The TAA applies to Government procurement contracts that equal or exceed certain threshold amounts. *See e.g.* 48 C.F.R. § 25.1101(c)(1); 48 C.F.R. § 225.1101(6); 78 Fed. Reg. 76700 (Dec. 18, 2013).[4]

29. Only specified countries qualify as TAA-designated countries of origin for products acquired by the United States Government.[5]

30. India, China, Brazil, and Russia are among the non-permitted countries of origin under the TAA.[6]

31. U.S. Government contracts over the specified threshold amounts include clauses that restrict the country of origin for items purchased by the U.S. Government.[7]

32. For an end product that consists of materials from more than one country, that end product's country of origin is the place where the materials have been "substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of

[3] 19 U.S.C. § 2502.

[4] For example, for calendar years 2012 and 2013, the TAA threshold amount for applicability was $202,000.00. 76 Fed. Reg. 76808, 76809 (Dec. 8, 2011). For calendar years 2014 and 2015, the TAA threshold amount for applicability was $204,000.00. 78 Fed. Reg. 76700 (Dec. 18, 2013). For calendar years 2016 and 2017, the TAA threshold amount for applicability was $191,000.00. 80 Fed. Reg. 77,694, 77695 (Dec. 15, 2015).

[5] *See* 48 C.F.R. § 52.225-5; 48 C.F.R. § 252.225-7021.

[6] *See*, *e.g.*, 48 C.F.R. § 52.225-5.

[7] *See e.g.*, 48 C.F.R. § 25.1101(c)(1) & (c)(2).

the article or articles from which it was so transformed." 19 U.S.C. § 2518(4)(B); 19 C.F.R. § 177.22(a).

33. The country of origin for a pharmaceutical product is the country in which the drug's active pharmaceutical ingredient ("**API**") was sourced or produced.

34. Defendant GSMS knows, as that term is defined in the FCA,[8] that the country of origin for the following pharmaceutical products it sold to the Government (pursuant to contracts requiring TAA-compliant end products) were not TAA-designated countries:

a. metoprolol succinate;

b. carbamazepine IR;

c. quetiapine fumarate;

d. ursodiol;

e. acyclovir;

f. losartan potassium;

g. labetalol HCL;

h. fexofenadine;

i. methocarbamol;

j. estradiol;

k. topiramate;

l. cefuroxime axetil;

m. atenolol;

[8] The FCA defines "knowingly" to "mean that a person, with respect to information-(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). Proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B).

n. bupropion XL; and

o. tamoxifen citrate.

35. As described more fully below, Defendant GSMS is knowingly selling non-TAA compliant pharmaceutical products to the United States in violation of the False Claims Act.

B. The Pharmaceutical Prime Vendor Program

36. The Pharmaceutical Prime Vendor Program ("**PPV Program**") is the contracting method used by the United States Government to distribute drugs and other pharmaceutical products to the nation's veterans and to certain other Federal Government agencies.

37. Through the PPV Program, the Department of Veterans Affairs ("**VA**") provides pharmaceutical products to various VA facilities, to the Indian Health Service ("**IHS**"), to the Bureau of Prisons ("**BoP**"), and to other governmental entities. Authorized State Veterans Homes that have sharing agreements with VA facilities are also eligible participants in the PPV Program.

38. The Defense Logistics Agency ("**DLA**") likewise provides pharmaceutical products to the Department of Defense ("**DoD**") and to other governmental entities through the PPV Program.

39. Under the PPV Program, pharmaceutical distributors, including Defendant GSMS, enter into contracts with the VA and the DLA. These government contracts establish a national contract price for specific pharmaceutical products to be distributed through the PPV Program.

40. Pursuant to these VA and DLA contracts, the contractor agrees to allow the designated VA and DLA/DoD Pharmaceutical Prime Vendors to deliver the specified pharmaceutical products to various governmental entities.

41. A Pharmaceutical Prime Vendor ("**PPV**") is an independent business entity that functions as the primary distributor of specified classes of products such as drugs and pharmaceutical products for purchasers like VA hospitals and DoD medical facilities.

42. Contractors, including Defendant GSMS, are required to provide the pharmaceutical products specified in the contract schedule at the prices established in the contract to designated PPVs for distribution to DoD, VA, BoP, IHS, and other governmental entities.

43. The PPVs place orders with the contractor for delivery to the PPVs, who, in turn, distribute the pharmaceutical products to various governmental participants.

44. Under the terms of a Government contract with the VA or DLA, pharmaceutical providers, including Defendant GSMS, agree to accept orders from PPVs and provide pharmaceutical products to the PPVs at the prices agreed to in the Government contract for use by the medical treatment facilities, formularies, and eligible beneficiaries served by those PPVs.

45. Pharmaceutical providers, including Defendant GSMS, are required to report the dollar value of all sales made under a VA or DLA contract by calendar quarter. These reported sales must include all sales made, whether shipped directly to the users or through PPVs.

46. Under the terms of a VA or DLA contract, pharmaceutical providers, including Defendant GSMS, are paid for the pharmaceutical products they deliver to PPVs by those PPVs using Government funds.

47. Defendant GSMS knowingly sold non-TAA compliant pharmaceutical products to the United States through the PPV program in violation of the False Claims Act.

48. TAA compliance is material to the Government. The Government regularly

rejects bids for national contracts to supply pharmaceutical products when the TAA-compliance provision is not satisfied.

VI. GSMS IS KNOWINGLY VIOLATING ITS GOVERNMENT CONTRACTS BY SUPPLYING NON-TAA COMPLIANT PHARMACEUTICAL PRODUCTS

49. As is described below in detail, the Government Contracts at issue in this Complaint required GSMS to supply the Government with TAA-compliant pharmaceutical products.

50. Defendant GSMS falsely certified its compliance with the Trade Agreements requirements of its Government contracts.

51. Because GSMS knowingly failed to supply TAA-compliant pharmaceutical products and because GSMS falsely certified and/or represented its compliance with the Trade Agreements provisions in its Government Contracts, the claims for payment identified below are false claims.

A. The Metoprolol Succinate Contract: VA Contract No. VA797P-13-C-0030

52. On November 1, 2012, the VA issued Solicitation No. VA797P-12-R-0028 seeking offers to supply its requirements of metoprolol succinate tablets.[9]

53. Metoprolol succinate is a generic version of the brand name drugs Lopressor, Metoprolol Tartrate, and Toprol-XL. It is a beta-blocker that is used to treat angina (chest pain) and hypertension (high blood pressure). It is also used to treat or prevent heart attacks.

54. By making an offer on Solicitation No. VA797P-12-R-0028, Defendant GSMS agreed to furnish and deliver metoprolol succinate tablets subject to the terms and conditions

[9] This solicitation also sought offers to supply doxepin HCL. However, that award is not at issue here.

specified in the solicitation.

55. On March 22, 2013, Defendant GSMS was awarded Contract No. VA797P-13-C-0030 to supply metoprolol succinate tablets to the VA pursuant to Solicitation No. VA797P-12-R-0028 (collectively the "**Metoprolol Succinate Contract**").

56. The Metoprolol Succinate Contract is a firm fixed price requirements contract whereby Defendant GSMS agreed to supply metoprolol succinate tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veterans Homes.

57. The Metoprolol Succinate Contract was for one base year, with two one-year option years.

58. The Metoprolol Succinate Contract has a contract award amount of $137,369,403.00. This award amount is an estimate of the total value of annual orders by the various government facilities for this drug.

59. The effective date of the base year of the Metoprolol Succinate Contract was April 29, 2013.

60. On April 9, 2014, the VA exercised the first one year option available under the Metoprolol Succinate Contract, permitting governmental entities to place orders under that contract from April 29, 2014 through April 28, 2015.

61. On April 6, 2015, the VA exercised the second one year option available under Metoprolol Succinate Contract, permitting governmental entities to place orders under that contract from April 29, 2015 through April 28, 2016.

62. The products awarded under the Metoprolol Succinate Contract are ordered and

distributed through the PPV Program.

63. The Metoprolol Succinate Contract specifies that PPVs will accept Government orders and payment for metoprolol succinate tablets on behalf of Defendant GSMS.

64. The Metoprolol Succinate Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DOD PPVs.

65. The governmental facilities served under the Metoprolol Succinate Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

66. The Metoprolol Succinate Contract provides that "A contract(s) will be awarded to the responsible offeror(s) that submits an offer(s) meeting the solicitation requirements, and is the lowest price technically acceptable."

67. The Metoprolol Succinate Contract also provides that the Government may terminate the contract for cause if Defendant GSMS fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant GSMS shall be liable to the Government for any and all rights and remedies provided by law.

68. The Metoprolol Succinate Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

69. The Metoprolol Succinate Contract specifically requires Defendant GSMS to comply with FAR provision 52.225-5, Trade Agreements (MAY 2012) (19 U.S.C. § 2501 *et seq*., 19 U.S.C. § 3301 note).

70. The Metoprolol Succinate Contract also specifically requires Defendant GSMS to certify that "each end product . . . is a U.S.-made, designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Metoprolol Succinate Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[10]

71. Defendant GSMS is required to certify Trade Agreements compliance on an annual basis.

72. By submission of its offer for the Metoprolol Succinate Contract and in its annual certifications, Defendant GSMS verified that its Trade Agreements certification of compliance was current, accurate, complete, applicable to this solicitation, and incorporated by reference.

73. However, contrary to GSMS's representations, the 100 mg and 200 mg metoprolol succinate tablets Defendant GSMS provided to governmental entities under Contract No. VA797P-13-C-0030 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (MAY 2012).

74. The 100 mg and 200 mg metoprolol succinate tablets supplied by Defendant GSMS under the Metoprolol Succinate Contract are end products of a non-TAA designated country of origin.

75. In order to obtain the Metoprolol Succinate Contract, additional option years under that contract, and payments pursuant to that contract, Defendant GSMS falsely represented

[10] No such determinations were made by the Contracting Officer.

that the metoprolol succinate it was selling to the Government was a "U.S. made or designated country end product."

76. Because the 100 mg and 200 mg metoprolol succinate tablets distributed by Defendant GSMS are not a product of a TAA designated county of origin, they are ineligible for government procurement under the express terms of Contract No. VA797P-13-C-0030.

77. Defendant GSMS falsely represented that the 100 mg and 200 mg metoprolol succinate it supplied under Contract No. VA797P-13-C-0030 was a TAA-compliant product.

78. Defendant GSMS's certifications that the 100 mg and 200 mg metoprolol succinate tablets supplied under Contract No. VA797P-13-C-0030 were made in the United States or in a TAA "designated country" were false. GSMS made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

79. As specified in the Metoprolol Succinate Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Metoprolol Succinate Contract, or option years under that contract, to Defendant GSMS and GSMS would not have been paid any money for metoprolol succinate tablets if GSMS had truthfully disclosed in its bid that the country of origin for the 100 mg and 200 mg metoprolol succinate tablets was a non-TAA country of origin.

80. All claims for payment for 100 mg and 200 mg metoprolol succinate tablets supplied by Defendant GSMS under Contract No. VA797P-13-C-0030 are false claims.

B. The Carbamazepine IR Contract: VA Contract No. VA797P-14-C-0004

81. On February 26, 2014, the VA issued Solicitation No. VA797P-14-R-0012 seeking offers to supply its requirements of carbamazepine IR tablets.

82. Carbamazepine IR is the generic version of the brand name drug Tegretol. It is an anti-convulsant that is used to manage seizures.

83. By making an offer on Solicitation No. VA797P-14-R-0012, Defendant GSMS agreed to furnish and deliver carbamazepine IR tablets subject to the terms and conditions specified in the solicitation.

84. On April 22, 2014, Defendant GSMS was awarded Contract No. VA797P-14-C-0004 to supply carbamazepine IR tablets to the VA pursuant to Solicitation No. VA797P-14-R-0012 (collectively the "**Carbamazepine IR Contract**").

85. The Carbamazepine IR Contract is a firm fixed price requirements contract whereby Defendant GSMS agreed to supply carbamazepine IR tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veterans Homes.

86. The Carbamazepine IR Contract is for one base year, with four one-year option years.

87. The Carbamazepine IR Contract has a contract award amount of $3,275,321.00. This award amount is an estimate of the total value of annual orders by the various government facilities for this drug.

88. The effective date of the base year of the Carbamazepine IR Contract was June 23, 2014.

89. On May 18, 2015, the VA exercised the first one year option available under the Carbamazepine IR Contract, permitting governmental entities to place orders under that contract from June 23, 2015 through June 22, 2016.

90. On May 12, 2016, the VA exercised the second one year option available under the Carbamazepine IR Contract, permitting governmental entities to place orders under that contract from June 23, 2016 through June 22, 2017.

91. On June 19, 2017, the VA exercised the third one year option available under the Carbamazepine IR Contract, permitting governmental entities to place orders under that contract from June 23, 2017 through June 22, 2018.

92. The products awarded under the Carbamazepine IR Contract are ordered and distributed through the PPV Program.

93. The Carbamazepine IR Contract specifies that PPVs will accept Government orders and payment for carbamazepine IR tablets on behalf of Defendant GSMS.

94. The Carbamazepine IR Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DOD PPVs.

95. The governmental facilities served under the Carbamazepine IR Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

96. The Carbamazepine IR Contract provides that "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

97. The Carbamazepine IR Contract also provides that the Government may terminate the contract for cause if Defendant GSMS fails to comply with any contract terms and conditions.

In the event of such a termination for cause, Defendant GSMS shall be liable to the Government for any and all rights and remedies provided by law.

98. The Carbamazepine IR Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

99. The Carbamazepine IR Contract specifically requires Defendant GSMS to comply with FAR provision 52.225-5, Trade Agreements (NOV 2013) (19 U.S.C. § 2501, *et seq*., 19 U.S.C. § 3301 note).

100. The Carbamazepine IR Contract also specifically requires Defendant GSMS to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Carbamazepine IR Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[11]

101. Defendant GSMS is required to certify Trade Agreements compliance on an annual basis.

102. By submission of its offer for the Carbamazepine IR Contract and in its annual certifications, GSMS verified that its Trade Agreements certification was current, accurate, complete, and applicable to this solicitation, and incorporated by reference.

103. However, contrary to GSMS's representations, the carbamazepine IR tablets Defendant GSMS provides to governmental entities under Contract No. VA797P-14-C-0004 are

[11] No such determinations were made by the Contracting Officer.

not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (NOV 2013).

104. The carbamazepine IR tablets supplied by Defendant GSMS under the Carbamazepine IR Contract are end products of a non-TAA designated country of origin.

105. In order to obtain the Carbamazepine IR Contract, additional option years under that contract, and payments pursuant to that contract, Defendant GSMS falsely represented that the carbamazepine IR it was selling to the Government was a "U.S. made or designated country end product."

106. Because the carbamazepine IR tablets distributed by Defendant GSMS are not a product of a TAA-designated county of origin, they were ineligible for government procurement under the express terms of Contract No. VA797P-14-C-0004.

107. Defendant GSMS falsely represented that the carbamazepine IR it supplied under Contract No. VA797P-14-C-0004 was a TAA-compliant product.

108. Defendant GSMS's certifications that the carbamazepine IR tablets supplied under Contract No. VA797P-14-C-0004 were made in the United States or in a TAA "designated country" were false. Defendant GSMS made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

109. As specified in the Carbamazepine IR Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Carbamazepine IR Contract, or option years under that contract, to Defendant GSMS and GSMS would not have been paid any money for carbamazepine IR tablets if GSMS had truthfully disclosed in its bid that the country of origin for the carbamazepine IR tablets was a non-TAA country of origin.

110. All claims for payment for the carbamazepine IR supplied by Defendant GSMS under Contract No. VA797P-14-C-0004 are false claims.

C. The Quetiapine Fumarate Contract: DLA Contract No. SPE2D2-16-D-0031

111. On June 22, 2015, the DLA issued Solicitation No. SPE2D2-15-R-0008 seeking offers to supply its requirements of quetiapine fumarate tablets.

112. Quetiapine fumarate is the generic version of the brand name drug Seroquel. It is an anti-psychotic drug that is used to treat certain mood or mental conditions including schizophrenia, bipolar disorder, as well as manic and depressive episodes associated with bipolar disorder.

113. By making an offer on Solicitation No. SPE2D2-15-R-0008, Defendant GSMS agreed to furnish and deliver quetiapine fumarate tablets subject to the terms and conditions specified in the solicitation.

114. On November 5, 2015, Defendant GSMS was awarded Contract No. SPE2D2-16-D-0031 to supply quetiapine fumarate tablets to the DLA pursuant to Solicitation No. SPE2D2-15-R-0008 (collectively the "**Quetiapine Fumarate Contract**").

115. The Quetiapine Fumarate Contract is a firm fixed price requirements contract whereby Defendant GSMS agreed to supply quetiapine fumarate tablets for distribution to federal government entities including the VA, DoD, IHS, and BoP.

116. The Quetiapine Fumarate Contract is for one base year, with four one-year option years.

117. The Quetiapine Fumarate Contract has an estimated total award amount of $16,066,183.55 over five years. This award amount is an estimate of the total value of annual

orders by the various government facilities for this drug.

118. The effective date of the base year of the Quetiapine Fumarate Contract was November 10, 2015.

119. On November 3, 2016, the DLA exercised the first one year option available under the Quetiapine Fumarate Contract, permitting governmental entities to continue placing orders under that contract until November 4, 2017.

120. The Quetiapine Fumarate Contract specifies that Defendant GSMS, as the awarded contractor, consents to allow PPVs to distribute the listed products at the prices established in that contract.

121. The Quetiapine Fumarate Contract requires Defendant GSMS to provide the products specified in the schedule at the prices established to all eligible DoD, VA, BoP and IHS customers.

122. The Quetiapine Fumarate Contract establishes a national supply source, in accordance with FAR 52.216-21 Requirements, to provide the drugs listed in the schedule for purchase by DLA and VA customers through the PPV.

123. The Quetiapine Fumarate Contract requires Defendant GSMS to accept orders from designated PPVs at the prices agreed to under the contract and to deliver Quetiapine Fumarate tablets to PPVs for distribution to DoD and VA medical treatment facilities, formularies, and eligible government beneficiaries.

124. The Quetiapine Fumarate Contract requires Defendant GSMS to establish a business relationship with the PPVs.

125. The Quetiapine Fumarate Contract identifies five PPVs. Cardinal Health of

Dublin, Ohio is one of the designated DOD PPVs.

126. The governmental facilities served under the Quetiapine Fumarate Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

127. The Quetiapine Fumarate Contract states that, "An award will be made to the responsible offeror whose proposal is determined to be technically acceptable and provides the lowest evaluated price. . . . To receive an acceptable rating for Technical Requirements, the offeror must accept all terms and conditions of the Statement of Work and Solicitation."

128. The Quetiapine Fumarate Contract also provides that the Government may terminate the contract for cause if Defendant GSMS fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant GSMS shall be liable to the Government for any and all rights and remedies provided by law.

129. The Quetiapine Fumarate Contract specifically requires Defendant GSMS to comply with DFARS 252.225-7021, Trade Agreements (NOV 2014).

130. The Quetiapine Fumarate Contract specifically states: "This solicitation is subject to DFARS 225.4 - Trade Agreements as implemented by DFARS 252.225-7021 contained in this solicitation. Additionally, evaluations will be in accordance with DFARS Subpart 225.5."

131. The Quetiapine Fumarate Contract specifically requires Defendant GSMS to deliver under this contract " only U.S.-made, qualifying country, or designated country end products . . . ." 48 C.F.R. 252.225-7021(c) (DFARS 252.225-7021 (c)).

132. By submission of its offer for the Quetiapine Fumarate Contract, Defendant GSMS verified that its Trade Agreements representations were current, accurate, complete, applicable to this solicitation, and incorporated by reference.

133. However, contrary to GSMS's representations, the quetiapine fumarate tablets Defendant GSMS provides to governmental entities under Contract No. SPE2D2-16-D-0031 are not U.S.-made, and are not qualifying country or designated country end products under the definitions provided in DFARS provision 252.225-7021, Trade Agreements (NOV 2014).

134. The quetiapine fumarate tablets supplied by Defendant GSMS under the Quetiapine Fumarate Contract are end products of non-TAA designated countries.

135. In order to obtain the Quetiapine Fumarate Contract, additional option years under that contract, and payments pursuant to that contract, Defendant GSMS falsely represented that the quetiapine fumarate it was selling to the Government was a "U.S. made, qualifying country, or designated country end product."

136. Because the quetiapine fumarate tablets distributed by Defendant GSMS are a product of a non-TAA designated country, they are ineligible for government procurement under the express terms of Contract No. SPE2D2-16-D-0031.

137. Defendant GSMS falsely represented that the quetiapine fumarate it supplied under Contract No. SPE2D2-16-D-0031 was a TAA-compliant product.

138. Defendant GSMS's certifications that the Quetiapine Fumarate tablets supplied under Contract No. SPE2D2-16-D-0031 were made in the United States or in a TAA "qualifying or designated country" were false. Defendant GSMS made these false certifications "knowingly," as that term is defined in 31 U.S.C. § 3729(b)(1).

139. As specified in the Quetiapine Fumarate Contract and reiterated in GSMS's annual representations and certifications, the Government would not have awarded the Quetiapine Fumarate Contract, or option years under that contract, to Defendant GSMS and GSMS would not have been paid any money for quetiapine fumarate tablets if GSMS had truthfully disclosed in its bid that the country of origin for the quetiapine fumarate tablets was a non-TAA country of origin.

140. All claims for payment for the quetiapine fumarate supplied by Defendant GSMS under Contract No. SPE2D2-16-D-0031 are false claims.

D. The Ursodiol Contract: VA Contract No. VA797P-16-C-0061

141. On February 26, 2016, the VA issued Solicitation No. VA797P-16-R-0041 seeking offers to supply its requirements of ursodiol capsules.

142. Ursodiol is a generic version of the brand name drugs Actigall and Urso. It is a bile acid that is used to dissolve certain types of gallstones, to prevent gallstones from forming in certain patients, and to treat a certain type of liver disease (primary biliary cirrhosis).

143. By making an offer on Solicitation No. VA797P-16-R-0041, Defendant GSMS agreed to furnish and deliver ursodiol capsules subject to the terms and conditions specified in the solicitation.

144. On June 6, 2016, Defendant GSMS was awarded Contract No. VA797P-16-C-0061 to supply ursodiol capsules to the VA pursuant to Solicitation No. VA797P-16-R-0041 (collectively the "**Ursodiol Contract**").

145. The Ursodiol Contract is a firm fixed price requirements contract whereby

Defendant GSMS agreed to supply ursodiol capsules for distribution to VA, DoD, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veterans Homes.

146. The Ursodiol Contract is for one base year, with four one-year option years.

147. The Ursodiol Contract has a contract award amount of $48,091,793.00. This award amount is an estimate of the total value of annual orders by the various government facilities for this drug.

148. The effective date of the base year of the Ursodiol Contract was August 6, 2016.

149. On July 6, 2017, the VA exercised the first one year option available under the Ursodiol Contract, permitting governmental entities to place orders under that contract from August 6, 2017 through August 5, 2018.

150. The products awarded under the Ursodiol Contract are ordered and distributed through the PPV Program.

151. The Ursodiol Contract specifies that PPVs will accept Government orders and payment for ursodiol capsules on behalf of Defendant GSMS.

152. The Ursodiol Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DOD PPVs.

153. The governmental facilities served under the Ursodiol Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

154. The Ursodiol Contract provides that "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

155. The Ursodiol Contract also provides that the Government may terminate the contract for cause if Defendant GSMS fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant GSMS shall be liable to the Government for any and all rights and remedies provided by law.

156. The Ursodiol Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

157. The Ursodiol Contract specifically requires Defendant GSMS to comply with FAR provision 52.225-5, Trade Agreements (Feb 2016) (19 U.S.C. § 2501 *et seq*., 19 U.S.C. § 3301 note).

158. The Ursodiol Contract also specifically requires Defendant GSMS to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Ursodiol Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[12]

159. Defendant GSMS is required to certify Trade Agreements compliance on an annual basis.

[12] No such determinations were made by the Contracting Officer.

160. By submission of its offer for the Ursodiol Contract and in its annual certifications, Defendant GSMS verified that its Trade Agreements certification of compliance was current, accurate, complete, applicable to this solicitation, and incorporated by reference.

161. However, contrary to GSMS's representations, the ursodiol capsules Defendant GSMS provides to governmental entities under Contract No. VA797P-16-C-0061 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (Feb 2016).

162. The ursodiol capsules supplied by Defendant GSMS under the Ursodiol Contract are end products of a non-TAA designated country of origin.

163. In order to obtain the Ursodiol Contract, additional option years under that contract, and payments pursuant to that contract, Defendant GSMS falsely represented that the ursodiol it was selling to the Government was a "U.S. made or designated country end product."

164. Because the ursodiol capsules distributed by Defendant GSMS are not a product of a TAA designated county of origin, they are ineligible for government procurement under the express terms of Contract No. VA797P-16-C-0061.

165. Defendant GSMS falsely represented that the ursodiol it supplied under Contract No. VA797P-16-C-0061 was a TAA-compliant product.

166. Defendant GSMS's certifications that the ursodiol capsules supplied under Contract No. VA797P-16-C-0061 were made in the United States or in a TAA "designated country" were false. GSMS made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

167. As specified in the Ursodiol Contract and reiterated in the Trade Agreements

Certificate, the Government would not have awarded the Ursodiol Contract, or option years under that contract, to Defendant GSMS and GSMS would not have been paid any money for ursodiol capsules if GSMS had truthfully disclosed in its bid that the country of origin for the ursodiol capsules was a non-TAA country of origin.

168. All claims for payment for the ursodiol supplied by Defendant GSMS under Contract No. VA797P-16-C-0061 are false claims.

E. The Acyclovir Contract: VA Contract No. VA797P-16-C-0063

169. On April 5, 2016, the VA issued Solicitation No. VA797P-16-R-0051 seeking offers to supply its requirements of acyclovir capsules and tablets.

170. Acyclovir is a generic version of the brand name drug Zovirax. It is an antiviral drug that is used to treat infections caused by the herpes viruses including genital herpes, cold sores, shingles, and chicken pox.

171. By making an offer on Solicitation No. VA797P-16-R-0051, Defendant GSMS agreed to furnish and deliver acyclovir capsules and tablets subject to the terms and conditions specified in the solicitation.

172. On June 9, 2016, Defendant GSMS was awarded Contract No. VA797P-16-C-0063 to supply acyclovir capsules and tablets to the VA pursuant to Solicitation No. VA797P-16-R-0051 (collectively the "**Acyclovir Contract**").

173. The Acyclovir Contract is a firm fixed price requirements contract whereby Defendant GSMS agreed to supply acyclovir capsules and tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veterans Homes.

174. The Acyclovir Contract is for one base year, with four one-year option years.

175. The Acyclovir Contract has a contract award amount of $8,886,639.35. This award amount is an estimate of the total value of annual orders by the various government facilities for this drug.

176. The effective date of the base year of the Acyclovir Contract was August 12, 2016.

177. On June 27, 2017, the VA exercised the first one year option available under the Acyclovir Contract, permitting governmental entities to place orders under that contract from August 12, 2017 through August 11, 2018.

178. The products awarded under the Acyclovir Contract are ordered and distributed through the PPV Program.

179. The Acyclovir Contract specifies that PPVs will accept Government orders and payment for acyclovir capsules and tablets on behalf of Defendant GSMS.

180. The Acyclovir Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DOD PPVs.

181. The governmental facilities served under the Acyclovir Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

182. The Acyclovir Contract provides that "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest

price technically acceptable offer."

183. The Acyclovir Contract also provides that the Government may terminate the contract for cause if Defendant GSMS fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant GSMS shall be liable to the Government for any and all rights and remedies provided by law.

184. The Acyclovir Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

185. The Acyclovir Contract specifically requires Defendant GSMS to comply with FAR provision 52.225-5, Trade Agreements (Feb 2016) (19 U.S.C. § 2501 *et seq*., 19 U.S.C. § 3301 note).

186. The Acyclovir Contract also specifically requires Defendant GSMS to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Acyclovir Contract also expressly states that "[T]he Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[13]

187. Defendant GSMS is required to certify Trade Agreements compliance on an annual basis.

188. By submission of its offer for the Acyclovir Contract and in its annual certifications, Defendant GSMS verified that its Trade Agreements certification of compliance

[13] No such determinations were made by the Contracting Officer.

was current, accurate, complete, applicable to this solicitation, and incorporated by reference.

189. However, contrary to GSMS's representations, the acyclovir tablets that Defendant GSMS provides to governmental entities under Contract No. VA797P-16-C-0063 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (Feb 2016).

190. The acyclovir tablets supplied by Defendant GSMS under the Acyclovir Contract are end products of a non-TAA designated country of origin.

191. In order to obtain the Acyclovir Contract, additional option years under that contract, and payments pursuant to that contract, Defendant GSMS falsely represented that the acylclovir it was selling to the Government was a "U.S. made or designated country end product."

192. Because the acyclovir tablets distributed by Defendant GSMS are not a product of a TAA designated county of origin, they are ineligible for government procurement under the express terms of Contract No. VA797P-16-C-0063.

193. Defendant GSMS falsely represented that the acyclovir tablets it supplied under Contract No. VA797P-16-C-0063 were a TAA-compliant product.

194. Defendant GSMS's certifications that the acyclovir tablets supplied under Contract No. VA797P-16-C-0063 were made in the United States or in a TAA "designated country" were false. GSMS made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

195. As specified in the Acyclovir Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Acyclovir Contract, or option years

under that contract, to Defendant GSMS and GSMS would not have been paid any money for acyclovir tablets if GSMS had truthfully disclosed in its bid that the country of origin for the acyclovir tablets was a non-TAA country of origin.

196. All claims for payment for the acyclovir tablets supplied by Defendant GSMS under Contract No. VA797P-16-C-0063 are false claims.

F. The Losartan Potassium Contract: VA Contract No. VA797P-16-C-0078

197. On July 12, 2016, the VA issued Solicitation No. VA797P-16-R-0068 seeking offers to supply its requirements of losartan potassium tablets.

198. Losartan potassium is a generic version of the brand name drug Cozaar. It is used to treat high blood pressure (hypertension) and to help protect the kidneys from damage due to diabetes. It is also used to lower the risk of strokes in certain patients.

199. By making an offer on Solicitation No. VA797P-16-R-0068, Defendant GSMS agreed to furnish and deliver losartan potassium tablets subject to the terms and conditions specified in the solicitation.

200. On September 19, 2016, Defendant GSMS was awarded Contract No. VA797P-16-C-0078 to supply losartan potassium tablets to the VA pursuant to Solicitation No. VA797P-16-R-0068 (collectively the "**Losartan Potassium Contract**").

201. The Losartan Potassium Contract is a firm fixed price requirements contract whereby Defendant GSMS agreed to supply losartan potassium tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veterans Homes.

202. The Losartan Potassium Contract is for one base year, with four one-year option

years.

203. The Losartan Potassium Contract has a contract award amount of $23,214,184.55. This award amount is an estimate of the total value of annual orders by the various government facilities for this drug.

204. The effective date of the base year of the Losartan Potassium Contract was November 25, 2016.

205. On November 8, 2017, the VA exercised the first one year option available under the Losartan Potassium Contract, permitting governmental entities to place orders under that contract from November 25, 2017 through November 24, 2018.

206. The products awarded under the Losartan Potassium Contract are ordered and distributed through the PPV Program.

207. The Losartan Potassium Contract specifies that PPVs will accept Government orders and payment for losartan potassium tablets on behalf of Defendant GSMS.

208. The Losartan Potassium Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DOD PPVs.

209. The governmental facilities served under the Losartan Potassium Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

210. The Losartan Potassium Contract provides that "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest

price technically acceptable offer."

211. The Losartan Potassium Contract also provides that the Government may terminate the contract for cause if Defendant GSMS fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant GSMS shall be liable to the Government for any and all rights and remedies provided by law.

212. The Losartan Potassium Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

213. The Losartan Potassium Contract specifically requires Defendant GSMS to comply with FAR provision 52.225-5, Trade Agreements (FEB 2016) (19 U.S.C. § 2501 *et seq*., 19 U.S.C. § 3301 note).

214. The Losartan Potassium Contract also specifically requires Defendant GSMS to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Losartan Potassium Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[14]

215. Defendant GSMS is required to certify Trade Agreements compliance on an annual basis.

216. By submission of its offer for the Losartan Potassium Contract and in its annual certifications, Defendant GSMS verified that its Trade Agreements certification of compliance

[14] No such determinations were made by the Contracting Officer.

was current, accurate, complete, applicable to this solicitation, and incorporated by reference.

217. However, contrary to GSMS's representations, the losartan potassium tablets Defendant GSMS provides to governmental entities under Contract No. VA797P-16-C-0078 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (FEB 2016).

218. The losartan potassium tablets supplied by Defendant GSMS under the Losartan Potassium Contract are end products of a non-TAA designated country of origin.

219. In order to obtain the Losartan Potassium Contract, additional option years under that contract, and payments pursuant to that contract, Defendant GSMS falsely represented that the losartan potassium it was selling to the Government was a "U.S. made or designated country end product."

220. Because the losartan potassium tablets distributed by Defendant GSMS are not a product of a TAA designated county of origin, they are ineligible for government procurement under the express terms of Contract No. VA797P-16-C-0078.

221. Defendant GSMS falsely represented that the losartan potassium it supplied under Contract No. VA797P-16-C-0078 was a TAA-compliant product.

222. Defendant GSMS's certifications that the losartan potassium supplied under Contract No. VA797P-16-C-0078 were made in the United States or in a TAA "designated country" were false. GSMS made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

223. As specified in the Losartan Potassium Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Losartan Potassium

Contract, or option years under that contract, to Defendant GSMS and GSMS would not have been paid any money for losartan potassium tablets if GSMS had truthfully disclosed in its bid that the country of origin for the losartan potassium tablets was a non-TAA country of origin.

224. All claims for payment for the losartan potassium supplied by Defendant GSMS under Contract No. VA797P-16-C-0078 are false claims.

G. The Labetalol HCL Contract: VA Contract No. VA797P-13-C-0011

225. On August 21, 2012, the VA issued Solicitation No. VA797P-12-R-0019 seeking *inter alia* offers to supply its requirements of labetalol HCL tablets.[15]

226. Labetalol HCL is a generic version of the brand name drug Trandate. It is used to treat hypertension.

227. By making an offer on Solicitation No. VA797P-12-R-0019, Defendant GSMS agreed to furnish and deliver labetalol HCL tablets subject to the terms and conditions specified in the solicitation.

228. On April 10, 2013, Defendant GSMS was awarded Contract No. VA797P-13-C-0011 to supply labetalol HCL tablets to the VA pursuant to Solicitation No. VA797P-12-R-0019 (collectively the "**Labetalol HCL Contract**").

229. The Labetalol HCL Contract is a firm fixed price requirements contract whereby Defendant GSMS agreed to supply labetalol HCL tablets for distribution to VA, DOD, IHS, and BOP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

230. The Labetalol HCL Contract is for one base year, with four one-year option years.

[15] In all, Solicitation No. VA797P-12-R-0019 sought proposals to supply five different drugs: fluoxetine capsules, fluphenazine tablets, topotecan injectables, cimetidine tablets and labetalol tablets. Only the award of the labetalol tablets is at issue here.

231. The Labetalol HCL Contract has a contract award amount of $19,942,880.00. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

232. The effective date of the base year of the Labetalol HCL Contract was May 20, 2013.

233. On May 19, 2014, the VA exercised the first one year option available under the Labetalol HCL Contract, permitting governmental entities to place orders under that contract from May 20, 2014 through May 19, 2015.

234. On April 7, 2015, the VA exercised the second one year option available under the Labetalol HCL Contract, permitting governmental entities to place orders under that contract from May 20, 2015 through May 19, 2016.

235. On April 19, 2016, the VA exercised the third one year option available under the Labetalol HCL Contract, permitting governmental entities to place orders under that contract from May 20, 2016 through May 19, 2017.

236. On May 1, 2017, the VA exercised the fourth and final one year option available under the Labetalol HCL Contract, permitting governmental entities to place orders under that contract from May 20, 2017 through May 19, 2018.

237. The products awarded under the Labetalol HCL Contract are ordered and distributed through the PPV Program.

238. The Labetalol HCL Contract specifies that PPVs will accept Government orders of labetalol HCL and payment for such orders on behalf of Defendant GSMS.

239. The Labetalol HCL Contract identifies one VA PPV and five DOD PPVs.

Cardinal Health of Dublin, Ohio is one of the designated DOD PPVs.

240. The governmental facilities served under the Labetalol Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

241. The Labetalol HCL Contract provides that "Contracts will be awarded to the responsible offeror that submits offers meeting the solicitation requirements, and are the lowest price technically acceptable."

242. The Labetalol HCL Contract also provides that the Government may terminate the contract for cause if Defendant GSMS fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant GSMS shall be liable to the Government for any and all rights and remedies provided by law.

243. The Labetalol HCL Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

244. The Labetalol HCL Contract specifically requires Defendant GSMS to comply with FAR provision 52.225-5, Trade Agreements (MAY 2012) (19 U.S.C. § 2501, *et seq*., 19 U.S.C. § 3301 note).

245. The Labetalol HCL Contract also specifically requires Defendant GSMS to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Labetalol HCL Contract also expressly states that "The Government will

consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[16]

246. Defendant GSMS is required to certify Trade Agreements compliance on an annual basis.

247. By submission of its offer for the Labetalol HCL Contract and in its annual certifications, Defendant GSMS verified that its Trade Agreements certification was current, accurate, complete, and applicable to this solicitation, and incorporated by reference.

248. However, contrary to GSMS's representations, the labetalol HCL tablets Defendant GSMS provides to governmental entities under Contract No. VA797P-13-C-0011 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (MAY 2012).

249. The labetalol HCL tablets supplied by Defendant GSMS under the Labetalol HCL Contract are end products of a non-TAA designated country of origin.

250. In order to obtain the Labetalol HCL Contract, additional option years under that contract, and payments pursuant to that contract, Defendant GSMS falsely represented that the labetalol HCL it was selling to the Government was a "U.S. made or designated country end product."

251. Because the labetalol HCL tablets distributed by Defendant GSMS are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-13-C-0011.

[16] No such determinations were made by the Contracting Officer.

252. Defendant GSMS falsely represented that the labetalol HCL it supplied under Contract No. VA797P-13-C-0011 was a TAA-compliant product.

253. Defendant GSMS's certifications that the labetalol HCL tablets supplied under Contract No. VA797P-13-C-0011 were made in the United States or in a TAA "designated country" were false. GSMS made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

254. As specified in the Labetalol HCL Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Labetalol HCL Contract, or option years under that contract, to Defendant GSMS and GSMS would not have been paid any money for labetalol HCL tablets if GSMS had truthfully disclosed in its bid that the country of origin for the labetalol HCL tablets was a non-TAA country of origin.

255. All claims for payment for the labetalol HCL tablets supplied by Defendant GSMS under Contract No. VA797P-13-C-0011 are false claims.

H. The Fexofenadine Contract: DLA Contract No. SPE2D2-14-D-0005

256. On January 29, 2014, the DLA issued Solicitation No. SPM2D0-14-R-N015 seeking offers to supply its requirements of fexofenadine tablets.

257. Fexofenadine is a generic version of the brand name drug Allegra. It is used to treat seasonal allergy symptoms as well as itching and hives caused by certain conditions.[17]

258. By making an offer on Solicitation No. SPM2D0-14-R-N015, Defendant GSMS agreed to furnish and deliver fexofenadine tablets subject to the terms and conditions specified in

[17] As issued, Solicitation No. SPM2D0-14-R-N015 sought proposals to supply fexofenadine tablets and olanzapine tablets. However, the schedule of supplies for Solicitation No. SPM2D0-14-R-N015 was immediately corrected to seek proposals to supply only fexofenadine tablets.

the solicitation.

259. On July 28, 2014, Defendant GSMS was awarded Contract No. SPE2D2-14-D-0005 to supply fexofenadine tablets to the DLA pursuant to Solicitation No. SPM2D0-14-R-N015 (collectively the "**Fexofenadine Contract**").

260. The Fexofenadine Contract is a firm fixed price requirements contract whereby Defendant GSMS agreed to supply fexofenadine tablets for distribution to Federal Government entities including the VA, DoD, IHS, and BoP.

261. The Fexofenadine Contract is for one base year, with four one-year option years.

262. The Fexofenadine Contract has an estimated total award amount of $32,950,166.40 over five years. This award amount is an estimate of the total value of annual orders by the various Government facilities for this drug.

263. The effective date of the base year of the Fexofenadine Contract was July 29, 2014.

264. On July 28, 2015, the DLA exercised the first one year option available under the Fexofenadine Contract, permitting governmental entities to continue placing orders under that contract.

265. On July 27, 2016, the DLA exercised the second option year available under the Fexofenadine Contract, permitting governmental entities to continue placing orders under that contract.

266. On July 20, 2017, the DLA exercised the third option year available under the Fexofenadine Contract, permitting governmental entities to continue placing orders under that contract.

267. The Fexofenadine Contract specifies that Defendant GSMS, as the awarded contractor, consents to allow VA and DoD PPVs to distribute the listed products at the prices established in that contract.

268. The Fexofenadine Contract requires Defendant GSMS to provide the products specified in the schedule at the prices established to all eligible DoD, VA, BoP, and IHS customers.

269. The Fexofenadine Contract establishes a national supply source, in accordance with FAR 52.216-21 Requirements, to provide the drugs listed in the schedule for purchase by DLA and VA customers through the PPV.

270. The Fexofenadine Contract requires Defendant GSMS to accept orders from designated PPVs at the prices agreed to under the contract and to deliver fexofenadine tablets to PPVs for distribution to DLA and VA medical treatment facilities, formularies, and eligible Government beneficiaries.

271. The Fexofenadine Contract requires Defendant GSMS to establish a business relationship with the PPVs.

272. The Fexofenadine Contract identifies five PPVs. Cardinal Health of Dublin, Ohio is one of the designated DOD PPVs.

273. The governmental facilities served under the Fexofenadine Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

274. The Fexofenadine Contract states that, "An award will be made to the responsible offeror whose proposal is determined to be technically acceptable and provides the lowest evaluated price. . . . To receive an acceptable rating for Technical Requirements, the offeror must accept all terms and conditions of the Statement of Work and Solicitation."

275. The Fexofenadine Contract provides that the Government may terminate the contract for cause if Defendant GSMS fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant GSMS shall be liable to the Government for any and all rights and remedies provided by law.

276. The Fexofenadine Contract specifically requires Defendant GSMS to comply with DFARS 252.225-7021, Trade Agreements (DEC 2012).

277. The Fexofenadine Contract specifically states: "This solicitation is subject to DFARS 225.4 - Trade Agreements as implemented by DFARS 252.225-7021 contained in this solicitation. Additionally, evaluations will be in accordance with DFARS Subpart 225.5."

278. DFARS 252.225-7021, Trade Agreements (DEC 2012), specifically requires Defendant GSMS to deliver under this contract "only U.S.-made, qualifying country, or designated country end products . . . ." 48 C.F.R. 252.225-7021(c) (DFARS 252.225-7021(c).

279. By submission of its offer for the Fexofenadine Contract, Defendant GSMS affirmed that its Trade Agreements representations were current, accurate, complete, applicable to this solicitation, and incorporated by reference.

280. However, contrary to GSMS's representations, the fexofenadine tablets Defendant GSMS provides to governmental entities under Contract No. SPE2D2-14-D-0005 are not U.S.-made, and are not qualifying country or designated country end products under the

definitions provided in DFARS provision 252.225-7021, Trade Agreements (DEC 2012).

281. The fexofenadine tablets supplied by Defendant GSMS under the Fexofenadine Contract are end products of a non-TAA designated country of origin.

282. In order to obtain the Fexofenadine Contract, additional option years under that contract, and payments pursuant to that contract, Defendant GSMS falsely represented that the fexofenadine it was selling to the Government was a "U.S. made, qualifying country, or designated country end product."

283. Because the fexofenadine tablets distributed by Defendant GSMS are not a product of a TAA designated country, they are ineligible for Government procurement under the express terms of Contract No. SPE2D2-14-D-0005.

284. Defendant GSMS falsely represented that the fexofenadine tablets it supplied under Contract No. SPE2D2-14-D-0005 were a TAA-compliant product.

285. Defendant GSMS's representations that the fexofenadine tablets supplied under Contract No. SPE2D2-14-D-0005 were made in the United States or in a TAA qualifying or designated country were false. GSMS made these false representations "knowingly," as that term is defined in 31 U.S.C. § 3729(b)(1).

286. As specified in the Fexofenadine Contract and reiterated in GSMS's annual representations and certifications, the Government would not have awarded the Fexofenadine Contract, or option years under that contract, to Defendant GSMS and GSMS would not have been paid any money for fexofenadine tablets if GSMS had truthfully disclosed in its bid that the country of origin for the fexofenadine tablets was a non-TAA country of origin.

287. All claims for payment for the fexofenadine tablets supplied by Defendant GSMS

under Contract No. SPE2D2-14-D-005 are false claims.

I. The Methocarbamol Contract: VA Contract No. VA797P-14-C-0003

288. On February 12, 2014, the VA issued Solicitation No. VA797P-14-R-0007 seeking offers to supply its requirements of methocarbamol tablets.

289. Methocarbamol is a generic version of the brand name drug Robaxin. It is used to treat skeletal muscle conditions such as pain or injury.

290. By making an offer on Solicitation No. VA797P-14-R-0007, Defendant GSMS agreed to furnish and deliver methocarbamol tablets subject to the terms and conditions specified in the solicitation.

291. On April 1, 2014, Defendant GSMS was awarded Contract No. VA797P-14-C-0003 to supply methocarbamol tablets to the VA pursuant to Solicitation No. VA797P-14-R-0007 (collectively the "**Methocarbamol Contract**").

292. The Methocarbamol Contract is a firm fixed price requirements contract whereby Defendant GSMS agreed to supply methocarbamol tablets for distribution to VA, DOD, IHS, and BOP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

293. The Methocarbamol Contract is for one base year, with three one-year option years.

294. The Methocarbamol Contract has a contract award amount of $23,346,760.00. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

295. The effective date of the base year of the Methocarbamol Contract was May 15, 2014.

296. On May 5, 2015, the VA exercised the first one year option available under the Methocarbamol Contract, permitting governmental entities to place orders under that contract from May 15, 2015 through May 14, 2016.

297. On April 4, 2016, the VA exercised the second one year option available under the Methocarbamol Contract, permitting governmental entities to place orders under that contract from May 15, 2016 through May 14, 2017.

298. On May 8, 2017, the VA exercised the third one year option available under the Methocarbamol Contract, permitting governmental entities to place orders under that contract from May 15, 2017 through May 14, 2018.

299. The products awarded under the Methocarbamol Contract are ordered and distributed through the PPV Program.

300. The Methocarbamol Contract specifies that PPVs will accept Government orders of methocarbamol and payment for such orders on behalf of Defendant GSMS.

301. The Methocarbamol Contract identifies one VA PPV and five DOD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DOD PPVs.

302. The governmental facilities served under the Methocarbamol Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

303. The Methocarbamol Contract provides that "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest

price technically acceptable offer."

304. The Methocarbamol Contract also provides that the Government may terminate the contract for cause if Defendant GSMS fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant GSMS shall be liable to the Government for any and all rights and remedies provided by law.

305. The Methocarbamol Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

306. The Methocarbamol Contract specifically requires Defendant GSMS to comply with FAR provision 52.225-5, Trade Agreements (NOV 2012) (19 U.S.C. § 2501, *et seq*., 19 U.S.C. § 3301 note).

307. The Methocarbamol Contract also specifically requires Defendant GSMS to certify that "each end product . . . is a U.S.-made, designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Methocarbamol Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[18]

308. GSMS is required to certify Trade Agreements compliance on an annual basis.

309. By submission of its offer for the Methocarbamol Contract and in its annual certifications, GSMS verified that its Trade Agreements certification was current, accurate, complete, and applicable to this solicitation, and incorporated by reference.

[18] No such determinations were made by the Contracting Officer.

310. However, contrary to GSMS's representations, the methocarbamol tablets Defendant GSMS provides to governmental entities under Contract No. VA797P-14-C-0003 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (NOV 2012).

311. The methocarbamol tablets supplied by Defendant GSMS under the Methocarbamol Contract are end products of a non-TAA designated country of origin.

312. In order to obtain the Methocarbamol Contract, additional option years under that contract, and payments pursuant to that contract, Defendant GSMS falsely represented that the methocarbamol it was selling to the Government was a "U.S. made or designated country end product."

313. Because the methocarbamol tablets distributed by Defendant GSMS are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-14-C-0003.

314. Defendant GSMS falsely represented that the methocarbamol it supplied under Contract No. VA797P-14-C-0003 was a TAA-compliant product.

315. Defendant GSMS's certifications that the methocarbamol tablets supplied under Contract No. VA797P-14-C-0003 were made in the United States or in a TAA "designated country" were false.

316. Defendant GSMS made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

317. As specified in the Methocarbamol Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Methocarbamol Contract,

or option years under that contract, to Defendant GSMS and GSMS would not have been paid any money for methocarbamol tablets if GSMS had truthfully disclosed in its bid that the country of origin for the methocarbamol tablets was a non-TAA country of origin.

318. All claims for payment for the methocarbamol tablets supplied by Defendant GSMS under Contract No. VA797P-14-C-0003 are false claims.

J. The Estradiol Contract: VA Contract No. VA797P-15-C-0029

319. On December 3, 2014, the VA issued Solicitation No. VA797P-15-R-0026 seeking offers to supply its requirements of estradiol tablets.

320. Estradiol is a brand name drug used to treat symptoms associated with menopause.

321. By making an offer on Solicitation No. VA797P-15-R-0026, Defendant GSMS agreed to furnish and deliver estradiol tablets subject to the terms and conditions specified in the solicitation.

322. On April 7, 2015, Defendant GSMS was awarded Contract No. VA797P-15-C-0029 to supply estradiol tablets to the VA pursuant to Solicitation No. VA797P-15-R-0026 (collectively the "**Estradiol Contract**").

323. The Estradiol Contract is a firm fixed price requirements contract whereby Defendant GSMS agreed to supply estradiol tablets for distribution to VA, DOD, IHS, and BOP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

324. The Estradiol Contract is for one base year, with four one-year option years.

325. The Estradiol Contract has a contract award amount of $1,292,217.00. This award amount is an estimate of the total value of all annual orders by the various Government facilities

for this drug.

326. The effective date of the base year of the Estradiol Contract was July 1, 2015.

327. On May 24, 2016, the VA exercised the first one year option available under the Estradiol Contract, permitting governmental entities to place orders under that contract from July 1, 2016 through June 30, 2017.

328. On June 21, 2017, the VA exercised the second one year option available under the Estradiol Contract, permitting governmental entities to place orders under that contract from July 1, 2017 through June 30, 2018.

329. The products awarded under the Estradiol Contract are ordered and distributed through the PPV Program.

330. The Estradiol Contract specifies that PPVs will accept Government orders of estradiol and payment for such orders on behalf of Defendant GSMS.

331. The Estradiol Contract identifies one VA PPV and five DOD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DOD PPVs.

332. The governmental facilities served under the Estradiol Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

333. The Estradiol Contract provides that "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

334. The Estradiol Contract also provides that the Government may terminate the contract for cause if Defendant GSMS fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant GSMS shall be liable to the Government for any and all rights and remedies provided by law.

335. The Estradiol Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

336. The Estradiol Contract specifically requires Defendant GSMS to comply with FAR provision 52.225-5, Trade Agreements (NOV 2013) (19 U.S.C. § 2501, *et seq*., 19 U.S.C. § 3301 note).

337. The Estradiol Contract also specifically requires Defendant GSMS to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Estradiol Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[19]

338. Defendant GSMS is required to certify Trade Agreements compliance on an annual basis.

339. By submission of its offer for the Estradiol Contract and in its annual certifications, Defendant GSMS verified that its Trade Agreements certification was current, accurate, and complete, and applicable to this solicitation, and incorporated by reference.

[19] No such determinations were made by the Contracting Officer.

340. However, contrary to GSMS's representations, the estradiol tablets Defendant GSMS provides to governmental entities under Contract No. VA797P-15-C-0029 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (NOV 2013).

341. The estradiol tablets supplied by Defendant GSMS under the Estradiol Contract are end products of a non-TAA designated country of origin.

342. In order to obtain the Estradiol Contract, additional option years under that contract, and payments pursuant to that contract, Defendant GSMS falsely represented that the estradiol it was selling to the Government was a "U.S. made or designated country end product."

343. Because the estradiol tablets distributed by Defendant GSMS are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-15-C-0029.

344. Defendant GSMS falsely represented that the estradiol it supplied under Contract No. VA797P-15-C-0029 was a TAA-compliant product.

345. Defendant GSMS's certifications that the estradiol tablets supplied under Contract No. VA797P-15-C-0029 were made in the United States or in a TAA "designated country" were false. Defendant GSMS made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

346. As specified in the Estradiol Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Estradiol Contract, or option years under that contract, to Defendant GSMS and GSMS would not have been paid any money for estradiol tablets if GSMS had truthfully disclosed in its bid that the country of origin for the

estradiol tablets was a non-TAA country of origin.

347. All claims for payment for the estradiol tablets supplied by Defendant GSMS under Contract No. VA797P-15-C-0029 are false claims.

K. The Topiramate Contract: VA Contract No. VA797P-15-C-0050

348. On June 9, 2015, the VA issued Solicitation No. VA797P-15-R-0064 seeking offers to supply its requirements of topiramate tablets.

349. Topiramate is a generic version of the brand name drug Topamax. It is an anti-convulsant that is used to treat seizures.

350. By making an offer on Solicitation No. VA797P-15-R-0064, Defendant GSMS agreed to furnish and deliver topiramate tablets subject to the terms and conditions specified in the solicitation.

351. On August 24, 2015, Defendant GSMS was awarded Contract No. VA797P-15-C-0050 to supply topiramate tablets to the VA pursuant to Solicitation No. VA797P-15-R-0064 (collectively the "**Topiramate Contract**").

352. The Topiramate Contract is a firm fixed price requirements contract whereby Defendant GSMS agreed to supply topiramate tablets for distribution to VA, DOD, IHS, and BOP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

353. The Topiramate Contract is for one base year, with four one-year option years.

354. The Topiramate Contract has a contract award amount of $13,603,093.00. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

355. The effective date of the base year of the Topiramate Contract was October 31,

2015.

356. On October 3, 2016, the VA exercised the first one year option available under the Topiramate Contract, permitting governmental entities to continue placing orders under that contract.

357. On September 25, 2017, the VA exercised the second one year option available under the Topiramate Contract, permitting governmental entities to place orders under that contract from October 31, 2017 through October 30, 2018.

358. The products awarded under the Topiramate Contract are ordered and distributed through the PPV Program.

359. The Topiramate Contract specifies that PPVs will accept Government orders of topiramate and payment for such orders on behalf of Defendant GSMS.

360. The Topiramate Contract identifies one VA PPV and five DOD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DOD PPVs.

361. The governmental facilities served under the Topiramate Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

362. The Topiramate Contract provides that "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

363. The Topiramate Contract also provides that the Government may terminate the

contract for cause if Defendant GSMS fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant GSMS shall be liable to the Government for any and all rights and remedies provided by law.

364. The Topiramate Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

365. The Topiramate Contract specifically requires Defendant GSMS to comply with FAR provision 52.225-5, Trade Agreements (NOV 2013) (19 U.S.C. § 2501, *et seq*., 19 U.S.C. § 3301 note).

366. The Topiramate Contract also specifically requires Defendant GSMS to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Topiramate Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[20]

367. Defendant GSMS is required to certify Trade Agreements compliance on an annual basis.

368. By submission of its offer for the Topiramate Contract and in its annual certifications, Defendant GSMS verified that its Trade Agreements certification was current, accurate, complete, and applicable to this solicitation, and incorporated by reference.

369. However, contrary to GSMS's representations, the topiramate tablets Defendant

[20] No such determinations were made by the Contracting Officer.

GSMS provides to governmental entities under Contract No. VA797P-15-C-0050 are not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (NOV 2013).

370. The topiramate tablets supplied by Defendant GSMS under the Topiramate Contract are end products of a non-TAA designated country of origin.

371. In order to obtain the Topiramate Contract, additional option years under that contract, and payments pursuant to that contract, Defendant GSMS falsely represented that the topiramate it was selling to the Government was a "U.S. made or designated country end product."

372. Because the topiramate tablets distributed by Defendant GSMS are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-15-C-0050.

373. Defendant GSMS falsely represented that the topiramate it supplied under Contract No. VA797P-15-C-0050 was a TAA-compliant product.

374. Defendant GSMS's certifications that the topiramate tablets supplied under Contract No. VA797P-15-C-0050 were made in the United States or in a TAA "designated country" were false. Defendant GSMS made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

375. As specified in the Topiramate Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Topiramate Contract, or option years under that contract, to Defendant GSMS and GSMS would not have been paid any money for topiramate tablets if GSMS had truthfully disclosed in its bid that the country of origin for the

topiramate tablets was a non-TAA country of origin.

376. All claims for payment for the topiramate tablets supplied by Defendant GSMS under Contract No. VA797P-15-C-0050 are false claims.

L. The Cefuroxime Axetil Contract: VA Contract No. VA797P-16-C-0055

377. On March 15, 2016, the VA issued Solicitation No. VA797P-16-R-0044 seeking offers to supply its requirements of cefuroxime axetil tablets.

378. Cefuroxime axetil is a generic version of the brand name drug Ceftin. It is used to treat or prevent bacterial infections.

379. By making an offer on Solicitation No. VA797P-16-R-0044, Defendant GSMS agreed to furnish and deliver cefuroxime axetil tablets subject to the terms and conditions specified in the solicitation.

380. On May 12, 2016, Defendant GSMS was awarded Contract No. VA797P-16-C-0055 to supply cefuroxime axetil tablets to the VA pursuant to Solicitation No. VA797P-16-R-0044 (collectively the "**Cefuroxime Axetil Contract**").

381. The Cefuroxime Axetil Contract is a firm fixed price requirements contract whereby Defendant GSMS agreed to supply cefuroxime axetil tablets for distribution to VA, DOD, IHS, and BOP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

382. The Cefuroxime Axetil Contract is for one base year, with four one-year option years.

383. The Cefuroxime Axetil Contract has a contract award amount of $2,128,908.00. This award amount is an estimate of the total value of all annual orders by the various

Government facilities for this drug.

384. The effective date of the base year of the Cefuroxime Axetil Contract was September 16, 2016.

385. On August 15, 2017, the VA exercised the first one year option available under the Cefuroxime Axetil Contract, permitting governmental entities to place orders under that contract from September 16, 2017 through September 15, 2018.

386. The products awarded under the Cefuroxime Axetil Contract are ordered and distributed through the PPV Program.

387. The Cefuroxime Axetil Contract specifies that PPVs will accept Government orders of cefuroxime axetil and payment for such orders on behalf of Defendant GSMS.

388. The Cefuroxime Axetil Contract identifies one VA PPV and five DOD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DOD PPVs.

389. The governmental facilities served under the Cefuroxime Axetil Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

390. The Cefuroxime Axetil Contract provides that "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

391. The Cefuroxime Axetil Contract also provides that the Government may terminate the contract for cause if Defendant GSMS fails to comply with any contract terms and conditions.

In the event of such a termination for cause, Defendant GSMS shall be liable to the Government for any and all rights and remedies provided by law.

392. The Cefuroxime Axetil Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

393. The Cefuroxime Axetil Contract specifically requires Defendant GSMS to comply with FAR provision 52.225-5, Trade Agreements (Feb 2016) (19 U.S.C. § 2501, *et seq*., 19 U.S.C. § 3301 note).

394. The Cefuroxime Axetil Contract also specifically requires Defendant GSMS to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Cefuroxime Axetil Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[21]

395. Defendant GSMS is required to certify Trade Agreements compliance on an annual basis.

396. By submission of its offer for the Cefuroxime Axetil Contract and in its annual certifications, Defendant GSMS verified that its Trade Agreements certification was current, accurate, complete, and applicable to this solicitation, and incorporated by reference.

397. However, contrary to GSMS's representations, the cefuroxime axetil tablets Defendant GSMS provides to governmental entities under Contract No. VA797P-16-C-0055 are

[21] No such determinations were made by the Contracting Officer.

not U.S.-made or designated country end products as defined in FAR provision 52.225-5, Trade Agreements (Feb 2016).

398. The cefuroxime axetil tablets supplied by Defendant GSMS under the Cefuroxime Axetil Contract are end products of a non-TAA designated country of origin.

399. In order to obtain the Cefuroxime Axetil Contract, additional option years under that contract, and payments pursuant to that contract, Defendant GSMS falsely represented that the cefuroxime axetil it was selling to the Government was a "U.S. made or designated country end product."

400. Because the cefuroxime axetil tablets distributed by Defendant GSMS are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-16-C-0055.

401. Defendant GSMS falsely represented that the cefuroxime axetil it supplied under Contract No.VA797P-16-C-0055 was a TAA-compliant product.

402. Defendant GSMS's certifications that the cefuroxime axetil tablets supplied under Contract No. VA797P-16-C-0055 were made in the United States or in a TAA "designated country" were false. Defendant GSMS made these false certifications "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

403. As specified in the Cefuroxime Axetil Contract and reiterated in the Trade Agreements Certificate, the Government would not have awarded the Cefuroxime Axetil Contract, or option years under that contract, to Defendant GSMS and GSMS would not have been paid any money for cefuroxime axetil tablets if GSMS had truthfully disclosed in its bid that the country of origin for the cefuroxime axetil tablets was a non-TAA country of origin.

404. All claims for payment for the cefuroxime axetil tablets supplied by Defendant GSMS under Contract No. VA797P-16-C-0055 are false claims.

M. The Atenolol Contract: DLA Contract No. SPE2D2-14-D-0008

405. On January 28, 2014, the DLA issued Solicitation No. SPM2D0-13-R-N016 seeking offers to supply its requirements of atenolol tablets.

406. Atenolol is a generic version of the brand name drug Tenormin. It is a beta-blocker that is used to treat angina and hypertension. It is also used to lower the risk of death after a heart attack.

407. By making an offer on Solicitation No. SPM2D0-13-R-N016, Defendant GSMS agreed to furnish and deliver atenolol tablets subject to the terms and conditions specified in the solicitation.

408. On September 22, 2014, Defendant GSMS was awarded Contract No. SPE2D2-14-D-0008 to supply atenolol tablets to the DLA pursuant to Solicitation No. SPM2D0-13-R-N016 (collectively the "**Atenolol Contract**").

409. The Atenolol Contract is a firm fixed price requirements contract whereby Defendant GSMS agreed to supply atenolol tablets for distribution to Federal Government entities including the VA, DoD, IHS, and BoP.

410. The Atenolol Contract is for one base year, with four one-year option years.

411. The Atenolol Contract has a contract award amount of $22,249,074.75. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

412. The effective date of the base year of the Atenolol Contract was September 22,

2014.

413. On September 21, 2015, the DLA exercised the first one year option available under the Atenolol Contract, permitting governmental entities to continue placing orders under that contract from September 22, 2015 through September 21, 2016.

414. The DLA subsequently exercised the second one year option available under the Atenolol Contract, permitting governmental entities to continue placing orders under that contract from September 22, 2016 through September 21, 2017.

415. On September 19, 2017, the DLA exercised the third one year option available under the Atenolol Contract, permitting governmental entities to continue placing orders under that contract from September 22, 2017 through September 21, 2018.

416. The Atenolol Contract specifies that Defendant GSMS, as the awarded contractor, consents to allow VA and DoD PPVs to distribute the listed products at the prices established in that contract.

417. The Atenolol Contract requires Defendant GSMS to provide the products specified in the schedule at the prices established to all eligible DoD, VA, BoP, and IHS customers.

418. The Atenolol Contract establishes a national supply source, in accordance with FAR 52.216-21 Requirements, to provide the drugs listed in the schedule for purchase by DLA and VA customers through the PPV.

419. The Atenolol Contract requires Defendant GSMS to accept orders from designated PPVs at the prices agreed to under the contract and to deliver atenolol tablets to PPVs for distribution to DLA and VA medical treatment facilities, formularies, and eligible

Government beneficiaries.

420. The Atenolol Contract requires Defendant GSMS to establish a business relationship with the PPVs.

421. The Atenolol Contract identifies five PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

422. The governmental facilities served under the Escitalopram Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

423. The Atenolol Contract states that, "An award will be made to the responsible offeror whose proposal is determined to be technically acceptable and provides the lowest evaluated price. . . . To receive an acceptable rating for Technical Requirements, the offeror must accept all terms and conditions of the Statement of Work and Solicitation."

424. The Atenolol Contract provides that the Government may terminate the contract for cause if Defendant GSMS fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant GSMS shall be liable to the Government for any and all rights and remedies provided by law.

425. The Atenolol Contract specifically requires Defendant GSMS to comply with DFARS 252.225-7021, Trade Agreements (OCT 2013).

426. The Atenolol Contract specifically states: "This solicitation is subject to DFARS 225.4 - Trade Agreements as implemented by DFARS 252.225-7021 contained in this

solicitation. Additionally, evaluations will be in accordance with DFARS Subpart 225.5."

427. DFARS 252.225-7021, Trade Agreements (OCT 2013), specifically requires Defendant GSMS to deliver under this contract "only U.S.-made, qualifying country, or designated country end products . . . ." unless otherwise specified. 48 C.F.R. 252.225-7021(c) (DFARS 252.225-7021(c)).

428. By submission of its offer for the Atenolol Contract, GSMS affirmed that its Trade Agreements representations were current, accurate, complete, applicable to this solicitation, and incorporated by reference.

429. However, contrary to GSMS's representations, the atenolol tablets Defendant GSMS provides to governmental entities under Contract No. SPE2D2-14-D-0008 are not U.S.-made, and are not qualifying country or designated country end products under the definitions provided in DFARS provision 252.225-7021, Trade Agreements (OCT 2013).

430. The atenolol tablets supplied by Defendant GSMS under the Atenolol Contract are end products of a non-TAA designated country of origin.

431. In order to obtain the Atenolol Contract, additional option years under that contract, and payments pursuant to that contract, Defendant GSMS falsely represented that the atenolol it was selling to the Government was a "U.S. made, qualifying country, or designated country end product."

432. Because the atenolol tablets distributed by Defendant GSMS are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. SPE2D2-14-D-0008.

433. Defendant GSMS falsely represented that the atenolol it supplied under Contract

No. SPE2D2-14-D-0008 was a TAA-compliant product.

434. Defendant GSMS's representations that the atenolol tablets supplied under Contract No. SPE2D2-14-D-0008 were made in the United States or in a TAA "qualifying or designated country" were false. GSMS made these false representations "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

435. As specified in the Atenolol Contract and reiterated in GSMS's annual representations and certifications, the Government would not have awarded the Atenolol Contract, or option years under that contract, to GSMS and GSMS would not have been paid any money for atenolol tablets if GSMS had truthfully disclosed in its bid that the country of origin for the atenolol tablets was a non-TAA country of origin.

436. All claims for payment for atenolol supplied by Defendant GSMS under Contract No. SPE2D2-14-D-0008 are false claims.

N. The Bupropion XL Contract: DLA Contract No. SPE2D2-15-D-0025

437. On May 26, 2015, the DLA issued Solicitation No. SPE2D2-15-R-0009 seeking offers to supply its requirements of bupropion XL tablets.

438. Bupropion XL is a generic version of the brand name drug Wellbutrin XL. It is an antidepressant medication that is used to treat major depressive disorder and seasonal affective disorder.

439. By making an offer on Solicitation No. SPE2D2-15-R-0009, Defendant GSMS agreed to furnish and deliver bupropion XL tablets subject to the terms and conditions specified in the solicitation.

440. On August 20, 2015, Defendant GSMS was awarded Contract No.

SPE2D2-15-D-0025 to supply bupropion XL tablets to the DLA pursuant to Solicitation No. SPE2D2-15-R-0009 (collectively the "**Bupropion XL Contract**").

441. The Bupropion XL Contract is a firm fixed price requirements contract whereby Defendant GSMS agreed to supply bupropion XL tablets for distribution to Federal Government entities including the VA, DoD, IHS, and BoP.

442. The Bupropion XL Contract is for one base year, with four one-year option years.

443. The Bupropion XL Contract has a contract award amount of $20,976,403.45. This award amount is an estimate of the total value of all annual orders by the various Government facilities for this drug.

444. The effective date of the base year of the Bupropion XL Contract was August 20, 2015.

445. On August 17, 2016, the DLA exercised the first one year option available under the Bupropion XL Contract, permitting governmental entities to continue placing orders under that contract.

446. On August 10, 2017, the DLA exercised the second one year option available under the Bupropion XL Contract, permitting governmental entities to continue placing orders under that contract.

447. The Bupropion XL Contract specifies that Defendant GSMS, as the awarded contractor, consents to allow VA and DoD PPVs to distribute the listed products at the prices established in that contract.

448. The Bupropion XL Contract requires Defendant GSMS to provide the products specified in the schedule at the prices established to all eligible DoD, VA, BoP, and IHS

customers.

449. The Bupropion XL Contract establishes a national supply source, in accordance with FAR 52.216-21 Requirements, to provide the drugs listed in the schedule for purchase by DLA and VA customers through the PPV.

450. The Bupropion XL Contract requires Defendant GSMS to accept orders from designated PPVs at the prices agreed to under the contract and to deliver bupropion XL tablets to PPVs for distribution to DLA and VA medical treatment facilities, formularies, and eligible Government beneficiaries.

451. The Bupropion XL Contract requires Defendant GSMS to establish a business relationship with the PPVs.

452. The Bupropion XL Contract identifies five PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

453. The governmental facilities served under the Bupropion XL Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

454. The Bupropion XL Contract states that, "An award will be made to the responsible offeror whose proposal is determined to be technically acceptable and provides the lowest evaluated price. . . . To receive an acceptable rating for Technical Requirements, the offeror must accept all terms and conditions of the Statement of Work and Solicitation."

455. The Bupropion XL Contract provides that the Government may terminate the

contract for cause if Defendant GSMS fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant GSMS shall be liable to the Government for any and all rights and remedies provided by law.

456. The Bupropion XL Contract specifically requires Defendant GSMS to comply with DFARS 252.225-7021, Trade Agreements (NOV 2014).

457. The Bupropion XL Contract specifically states: "This solicitation is subject to DFARS 225.4 - Trade Agreements as implemented by DFARS 252.225-7021 contained in this solicitation. Additionally, evaluations will be in accordance with DFARS Subpart 225.5."

458. DFARS 252.225-7021, Trade Agreements (NOV 2014), specifically requires Defendant GSMS to deliver under this contract "only U.S.-made, qualifying country, or designated country end products . . . ." unless otherwise specified. 48 C.F.R. 252.225-7021(c) (DFARS 252.225-7021(c)).

459. By submission of its offer for the Bupropion XL Contract, GSMS affirmed that its Trade Agreements representations were current, accurate, complete, applicable to this solicitation, and incorporated by reference.

460. However, contrary to GSMS's representations, the bupropion XL tablets Defendant GSMS provides to governmental entities under Contract No. SPE2D2-15-D-0025 are not U.S.-made, and are not qualifying country or designated country end products under the definitions provided in DFARS provision 252.225-7021, Trade Agreements (NOV 2014).

461. The bupropion XL tablets supplied by Defendant GSMS under the Bupropion XL Contract are end products of a non-TAA designated country of origin.

462. In order to obtain the Bupropion XL Contract, additional option years under that

contract, and payments pursuant to that contract, Defendant GSMS falsely represented that the bupropion XL it was selling to the Government was a "U.S. made, qualifying country, or designated country end product."

463. Because the bupropion XL tablets distributed by Defendant GSMS are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. SPE2D2-15-D-0025.

464. Defendant GSMS falsely represented that the bupropion XL it supplied under Contract No. SPE2D2-15-D-0025 was a TAA-compliant product.

465. Defendant GSMS's representations that the bupropion XL tablets supplied under Contract No. SPE2D2-15-D-0025 were made in the United States or in a TAA "qualifying or designated country" were false. GSMS made these false representations "knowingly," as that term is defined 31 U.S.C § 3729(b)(1).

466. As specified in the Bupropion XL Contract and reiterated in GSMS's annual representations and certifications, the Government would not have awarded the Bupropion XL Contract, or option years under that contract, to GSMS and GSMS would not have been paid any money for bupropion XL tablets if GSMS had truthfully disclosed in its bid that the country of origin for the bupropion XL tablets was a non-TAA country of origin.

467. All claims for payment for bupropion XL supplied by Defendant GSMS under Contract No. SPE2D2-15-D-0025 are false claims.

O. The Tamoxifen Citrate Contract: VA Contract No. VA797P-17-C-0005

468. On September 15, 2016, the VA issued Solicitation No. VA797P-16-R-0102 seeking offers to supply its requirements of tamoxifen citrate tablets.

469. On September 29, 2016, Solicitation No. VA797P-16-R-0102 was modified to change the estimated quantities.

470. Tamoxifen citrate is a generic version of the brand name drug Soltamox. It is used to treat specific types of breast cancer and to reduce the risk of developing breast cancer in certain patients.

471. By making an offer on Solicitation No.VA797P-16-R-0102, Defendant GSMS agreed to furnish and deliver tamoxifen citrate tablets subject to the terms and conditions specified in the solicitation.

472. On November 15, 2016, Defendant GSMS was awarded Contract No. VA797P-17-C-0005 to supply tamoxifen citrate tablets to the VA pursuant to Solicitation No. VA797P-16-R-0102 (collectively the "**Tamoxifen Citrate Contract**").

473. The Tamoxifen Citrate Contract is a firm fixed price requirements contract whereby Defendant GSMS agreed to supply tamoxifen citrate tablets for distribution to VA, DoD, IHS, and BoP facilities, as well as to Federal Health Care Centers and to specified State Veteran Homes.

474. The Tamoxifen Citrate Contract is for one base year, with four one-year option years.

475. The Tamoxifen Citrate Contract has a contract award amount of $1,877,443.75. This award amount is an estimate of the total value of annual orders by the various Government facilities for this drug.

476. The effective date of the base year of the Tamoxifen Citrate Contract was January 14, 2017.

477. On January 3, 2018, the VA exercised the first one year option available under the Tamoxifen Citrate Contract, permitting governmental entities to place orders under that contract from January 14, 2018 until January 13, 2019.

478. The products awarded under the Tamoxifen Citrate Contract are ordered and distributed through the PPV Program.

479. The Tamoxifen Citrate Contract specifies that PPVs will accept Government orders for tamoxifen citrate tablets and payment for such orders on behalf of Defendant GSMS.

480. The Tamoxifen Citrate Contract identifies one VA PPV and five DoD PPVs. Cardinal Health of Dublin, Ohio is one of the designated DoD PPVs.

481. The governmental facilities served under the Tamoxifen Citrate Contract include the VA Medical Center located at 3200 Vine Street, Cincinnati, Ohio 45220; the VA Medical Center Dayton located at 4100 West Third Street, Dayton, Ohio 45428; the VA Medical Center located at 4337 Union Road, Middletown, Ohio 45005, and the VA Outpatient Clinic located at 512 South Burnett Road, Springfield, Ohio 45505.

482. The Tamoxifen Citrate Contract provides that, "A contract will be awarded to the responsible offeror that submits an offer meeting the solicitation requirements, and is the lowest price technically acceptable offer."

483. The Tamoxifen Citrate Contract also provides that the Government may terminate the contract for cause if Defendant GSMS fails to comply with any contract terms and conditions. In the event of such a termination for cause, Defendant GSMS shall be liable to the Government for any and all rights and remedies provided by law.

484. The Tamoxifen Citrate Contract provides that all delivery orders under that contract "are subject to the terms and conditions of this contract."

485. The Tamoxifen Citrate Contract specifically requires Defendant GSMS to comply with FAR 52.225-5, Trade Agreements (FEB 2016) (19 U.S.C. § 2501 *et seq*., 19 U.S.C. § 3301 note).

486. The Tamoxifen Citrate Contract also specifically requires Defendant GSMS to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled 'Trade Agreements'" and to list non-compliant end products. This provision of the Tamoxifen Citrate Contract also expressly states that "The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation."[22]

487. Defendant GSMS is required to certify Trade Agreements compliance on an annual basis.

488. By submission of its offer for the Tamoxifen Citrate Contract and in its annual certifications, Defendant GSMS verified that its Trade Agreements certifications were current, accurate, complete, applicable to this solicitation, and incorporated by reference.

489. However, contrary to GSMS's representations, the tamoxifen citrate tablets Defendant GSMS provides to governmental entities under Contract No. VA797P-17-C-0005 are not U.S.-made or designated country end products as defined in FAR 52.225-5, Trade Agreements (FEB 2016).

[22] No such determinations were made by the Contracting Officer.

490. The tamoxifen citrate tablets supplied by Defendant GSMS under the Tamoxifen Citrate Contract are end products of a non-TAA designated country of origin.

491. In order to obtain the Tamoxifen Citrate Contract, additional option years under that contract, and payments pursuant to that contract, Defendant GSMS falsely represented that the tamoxifen citrate it was selling to the Government was a "U.S. made or designated country end product."

492. Because the tamoxifen citrate tablets distributed by Defendant GSMS are not a product of a TAA-designated country of origin, they are ineligible for Government procurement under the express terms of Contract No. VA797P-17-C-0005.

493. Defendant GSMS falsely represented that the tamoxifen citrate it supplied under Contract No. VA797P-17-C-0005 was a TAA-compliant product.

494. Defendant GSMS's certifications that the tamoxifen citrate tablets supplied under Contract No. VA797P-17-C-0005 were made in the United States or in a TAA "designated country" were false. Defendant GSMS made these false certifications "knowingly," as that term is defined in 31 U.S.C § 3729(b)(1).

495. As specified in the Tamoxifen Citrate Contract and reiterated in the Trade Agreements Certificates, the Government would not have awarded the Tamoxifen Citrate Contract, or option years under that contract, to Defendant GSMS and GSMS would not have been paid any money for tamoxifen citrate tablets if GSMS had truthfully disclosed in its bid that the country of origin for the tamoxifen citrate tablets was a non-TAA country of origin.

496. All claims for payment for the tamoxifen citrate supplied by Defendant GSMS under Contract No. VA797P-17-C-0005 are false claims.

COUNT I-VIOLATION OF 31 U.S.C. § 3729(A)(1)(A)

497. Relators incorporate by reference and re-allege the preceding paragraphs as if fully restated.

498. Defendant GSMS, by and through its officers, members, agents, and employees, authorized the actions related to the conduct alleged above.

499. By virtue of the conduct described above, Defendant GSMS knowingly presented or caused to be presented false or fraudulent claims for payment in violation of 31 U.S.C. § 3729(a)(1)(A).

500. Defendant GSMS "knowingly" violated the False Claims Act, as that term is defined in 31 U.S.C. § 3729(b)(1). As to each of the above allegations, Defendant GSMS acted with actual knowledge of the information, in deliberate ignorance of the truth or falsity of the information, and/or in reckless disregard of the truth or falsity of the information.

501. As a result of Defendant GSMS's violations of 31 U.S.C. § 3729(a)(1)(A), the Government has suffered actual damages in an amount to be determined at trial.

COUNT II-VIOLATION OF 31 U.S.C. § 3729(A)(1)(B)

502. Relators incorporate by reference and re-allege the preceding paragraphs as if fully restated.

503. Defendant GSMS, by and through its officers, members, agents, and employees, authorized the actions related to the conduct alleged above.

504. By virtue of the conduct described above, Defendant GSMS knowingly made,

used or caused to be made or used, false records or statements material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B).

505. Defendant GSMS "knowingly" violated the False Claims Act, as that term is defined in 31 U.S.C. § 3729(b)(1). As to each of the above allegations, Defendant GSMS acted with actual knowledge of the information, in deliberate ignorance of the truth or falsity of the information, and/or in reckless disregard of the truth or falsity of the information.

506. As a result of Defendant GSMS's violations of 31 U.S.C. § 3729(a)(1)(B), the Government has suffered actual damages in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE Relators, on behalf of themselves and the United States, pray for judgment against Defendant GSMS as follows:

A. That this Court enter judgment against Defendant GSMS in an amount equal to three times the amount of damages sustained by the United States because of Defendant GSMS's acts in violation of the False Claims Act, plus the maximum civil penalty for each violation of the False Claims Act, as provided by 31 U.S.C. § 3729(a)(1);

B. That Relators be awarded all reasonable expenses incurred, plus reasonable attorneys' fees and costs, in accord with 31 U.S.C. § 3730(d);

C. That, in the event the United States intervenes, that Relators be awarded 25% of the proceeds of the action or of any settlement, in accord with 31 U.S.C. § 3730(d)(1);

D. That, in the event the United States does not intervene, that Relators be awarded 30% of the proceeds of the action or of any settlement, in accord with 31 U.S.C. § 3730(d)(2);

E. That Relators be awarded a share of any alternate remedy that the United States elects to pursue;

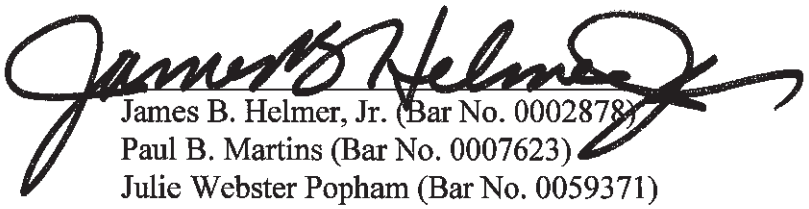
F. That Defendant GSMS be found to have violated the False Claims Act and be enjoined from future violations of that act;

G. That the United States and Relators be awarded pre-judgment and post-judgment interest; and

H. That the United States and Relators receive all relief, both at law and in equity to which they may be reasonably entitled.

Respectfully submitted,

Date: April 9, 2018



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CERTIFICATE OF SERVICE

I hereby certify that on April 9, 2018 , I served the foregoing:

Via Federal Express and Certified U.S. Mail upon:
Hon. Jefferson B. Sessions
Attorney General of the United States
United States Department of Justice
950 Pennsylvania Avenue N.W.
Washington, D.C. 20530

Via Hand Delivery upon:
Hon. Benjamin C. Glassman
United States Attorney
Hon. William B. King II
Assistant United States Attorney
221 E. Fourth Street, Suite 400
Cincinnati, OH 45202

Julie W. Popham